

**SPG 1280.1 Basic
July 2002**

John C. Stennis Space Center Management Manual



National Aeronautics and
Space Administration

John C. Stennis Space Center
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PREFACE

P.1 PURPOSE

Stennis Space Center's (SSC) roles and missions are established and managed using the NASA Strategic Management Process as defined in NPG 1000.2, NASA Strategic Management Handbook. This management process ensures alignment between the NASA Strategic Plan (NPD 1000.1), the Enterprise Strategic Plans, and the Center's implementation. SSC is the Agency's Program Manager for testing rocket propulsion systems for the Space Shuttle and future space vehicle propulsion systems. Likewise, due to its role in the Earth Science Enterprise, SSC is NASA's Program Manager for earth science applications. Because of these roles, SSC processes demand the highest quality in every aspect of the work we perform.

This Stennis Procedure and Guideline (SPG), John C. Stennis Space Center Management Manual (SMM), under the Center Director's control, is the basic manual providing information for the organizational structure, responsibilities, procedures, processes, and resources for implementing ANSI/ISO/ASQ Q9001 in accordance with NPD 8730.3, NASA Quality Management System Policy (ISO 9000). Adherence to the ISO 9001 requirements involves a disciplined approach to the design, development, production, and verification of our work efforts. This SPG is a top-level requirements document referencing lower-tier documents that provide more detailed requirements and instructions.

This SPG establishes a Stennis Quality Management System (QMS) to ensure consistent quality of NASA SSC products and services and the safety of our customers, employees, and products. Its benefits are measured in the quality of the work we perform and our compliance with customers' requirements. The scope of the QMS encompasses the research, design, and development of rocket propulsion test services and earth science applications provided by SSC. SSC also supports the NASA Agency infrastructure and is a major contributor to its scientific and technical enterprises.

P.2 APPLICABILITY

This SPG applies to all NASA and NASA contractor personnel engaged in the research, design, and development of propulsion test services and earth science applications.

P.3 AUTHORITY

- a. 42 U.S.C. 2473 (c)(1) of the National Aeronautics and Space Act of 1958, as amended.
- b. NPD 8730.3, NASA Quality Management System Policy (ISO 9000).

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P.4 REFERENCES

All references are assumed to be the latest version unless otherwise specified.

- a. ANSI/ISO/ASQ Q9000-2000, American National Standard, Quality Management Systems – Fundamentals and Vocabulary.
- b. ANSI/ISO/ASQ Q9001-2000, American National Standard, Quality Management Systems – Requirements.
- c. ANSI/ISO/ASQ Q9004-2000, American National Standard, Quality Management Systems – Guidelines for Performance Improvements.
- d. NPD 1440.6, NASA Records Management.
- e. NPD 1000.1, NASA Strategic Plan.
- f. NPD 8730.3, NASA Quality Management System Policy (ISO 9000).
- g. NPG 1000.2, NASA Strategic Management Handbook.
- h. NPG 1441.1, NASA Records Retention Schedules.
- i. NPG 7120.5, Program and Project Management System Requirements.
- j. OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Standards.
- k. SPD 5100.1, Policy for Ordering Materials and Support Services at SSC.
- l. SPD 7120.1, Stennis Space Center (SSC) Program/Project Risk Management.
- m. SPD 8730.3, S&MA Procurement Assurance Review Policy.
- n. SPG 1107.1, SSC Organization Mission and Responsibilities.
- o. SPG 1152.1, SSC/NASA Charters – Boards/Councils/Committees.
- p. SPG 1400.1, Document Preparation, Numbering, and Management Guidelines and Standards.
- q. SPG 7120.1, Stennis Space Center (SSC) Risk Management.
- r. SLP-06, Purchasing.
- s. SLP-08, Product Identification and Traceability.
- t. SLP-09, Process Control.
- u. SLP-13, Control of Nonconforming Product.
- v. SLP-15, Handling, Storage, Packaging, Preservation, and Delivery.
- w. SLP-20, Statistical Techniques.
- x. SSLP-1050-0001, Customer Agreement, Review and Coordination.
- y. SSLP-1280-0004, Internal Quality Audits.
- z. SSLP-1280-0010, Inspection and Testing.
- aa. SSLP-1410-0001, Document and Data Control.
- bb. SSLP-1440-0001, SSC Records Management Program and Control of Quality Records.
- cc. SSLP-3410-0001, Training.
- dd. SSLP-4210-0001, Control of Customer Property.
- ee. SSLP-8060-0001, Design Control.
- ff. SSLP-8720-0001, Control of Inspection, Measurement, and Test Equipment.
- gg. SSLP-8730-0004, Corrective/Preventive Action and Improvement.

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- hh. SSTD-8070-0005-CONFIG, Preparation, Approval and Release of Standards.
- ii. PTD-OI-E05, Facility Design Requirements.
- jj. RA-97-02, Facilities Construction Configuration Management Manual.
- kk. SCWI-3410-0002, Training and Development Plan.
- ll. SOI-8074-0001, Protection of Critical Information Resources.
- mm. SOI-8080-0006, Development and Approval of Customer Agreements.
- nn. SOI-8080-0015, Configuration Control of Propulsion Test Systems.
- oo. SWI-1280-0002-ESAD, Customer Relations.

P.5 CANCELLATION

SPG 8730.1, Customer Service Manual.

Roy S. Estess
Director

Original Signed By

Attachment

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CHAPTER 1. RESPONSIBILITIES

1.1 SSC Center Director

The total operational control of SSC rests with the Center Director. SSC's Management Manual is owned by the Center Director who is specifically responsible for its periodic review. The Center Director authorizes approval of revisions after an internal review by the QMC. The Director is responsible for ensuring implementation and effectiveness of this management system, as well as maintaining a work environment wherein all employees recognize safety and quality as the highest priorities.

The Center Director is responsible for ensuring that the SSC products meet customers' requirements and that the processes, procedures, and configuration management applied to product development are defined, followed correctly, and maintained. The SSC Center Director is responsible for providing sufficient resources (including trained personnel) for management, performance of work, verification, and auditing functions.

1.2 Quality Management Council

The Quality Management Council (QMC), composed of management representatives from throughout SSC, renders decisions, assigns actions, and tracks those actions to closure. Membership and operation of the QMC is defined under SPG 1152.1, SSC/NASA Charters – Boards/Councils/Committees. The chair and members have the responsibility to manage the implementation, maintenance, status, and improvement of the quality system. The QMC assesses opportunities for improvement and the need for changes to the QMS, including quality policy and quality objectives.

1.3 Management Representative for Quality

The SSC Center Director has appointed by letter a centerwide Management Representative for Quality (MRQ). Responsibility and authority to ensure that the system is established and maintained in accordance with the ISO 9001 standard is delegated to the MRQ. In addition, the MRQ reports on system performance to the Quality Management Council as a basis for review and improvement. The MRQ also ensures the promotion and awareness of customer requirements throughout the organization. The management representative also acts as the primary communications point for liaison with external bodies affecting the scope of ISO 9001 registration. The MRQ is responsible for maintenance of the SMM.

1.4 All Managers

Top management of each NASA and contractor organization is responsible for communicating and implementing the quality management system within their individual work areas and ensuring that their employees operate in strict compliance with applicable standards, regulations, specifications, and procedures. They support their employees by removing barriers that prevent

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quality in any work process. They establish and maintain work processes that consistently yield the desired product and service quality.

1.5 All Employees

All employees are responsible for the quality of their work and for understanding and complying with the requirements of this document, NASA and SSC PDs and PGs, System Level Procedures (SSLP) or Work Instructions (WI). Employees are responsible for stopping the work process or making appropriate notification when the process is unsafe or when the required quality is not being produced.

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CHAPTER 2. ORGANIZATION AND ADMINISTRATION PROCESSES

2.0 Organization and Administration (1000-1999)

SSC maintains documented procedures/instructions for general management, administrative processes, and safety to continually improve their effectiveness.

The following processes are managed in accordance with the Agency Filing Scheme (AFS) (e.g. 10XX) designation for organization and administration series documents:

- General (10XX)
- Organizational Structure (11XX)
- Internal Management Controls (12XX)
- External Relationships (13XX)
- Administrative Management Programs (14XX)
- Administrative Services (15XX)
- Security (16XX)
- Safety (17XX)
- Occupational Health (18XX)
- Standards of Conduct (19XX)

2.1 Management Responsibility

2.1.1 Management Commitment

SSC senior management provides evidence of its commitment to the development and implementation of the QMS and continually improving its effectiveness by:

- Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- Establishing the quality policy,
- Ensuring that quality objectives are established,
- Conducting management reviews, and
- Ensuring the availability of resources.

SSC senior management ensures that the integrity of the QMS is maintained when changes are planned and implemented. Senior management ensures that appropriate communication processes are established within SSC and that communication takes place regarding the effectiveness of the QMS.

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2.1.2 Quality Policy

SSC policy is to provide quality products and services to our customers through the Stennis values: people, customers, excellence, teamwork, and innovation. The SSC values serve as the principles that guide our decisions and behaviors. Our quality policy at SSC is:

Each of us, in whatever we do to support propulsion test, earth science applications, and operations support, is committed to continually improving the quality of our workforce and processes in meeting or exceeding customer needs.

Each SSC manager is responsible for ensuring the quality policy is understood, implemented, and maintained at all levels of the organization. This quality policy is communicated throughout the organization via ISO orientation, team meetings, employee training, and reviews with management.

2.1.3 Quality Objectives

Objectives of the SSC QMS are to:

- a. Conduct operations and processes safely while meeting annually established Safety Management Council objectives,
- b. Meet negotiated performance requirements,
- c. Meet negotiated major schedule milestones,
- d. Meet negotiated cost within program/project established guidelines, and
- e. Maintain a minimum overall customer satisfaction level of 98 percent.

2.1.4 Management Review

Status of the QMS is formally reported to the QMC at least quarterly. These reviews are conducted and records are kept to ensure the continuing suitability, adequacy, and effectiveness of the QMS. The input to these management reviews includes:

- Information on results of audits,
- Customer feedback,
- Process performance and product conformity,
- Status of preventive and corrective actions,
- Follow-up actions from previous management reviews,
- Changes that could affect the QMS, and
- Recommendations for improvement.

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The output from these management reviews includes:

- a. Any decisions and actions related to improvement of the effectiveness of the QMS and its processes, and
- b. Improvement of the products related to customer requirements, and resource needs.

2.1.5 Organization

Organizational charters are documented in SPG 1107.1, SSC Organization Mission and Responsibilities. Responsibility and authority for employees are defined in the employee's performance plan and through process and/or procedural documentation. Individual performance plans and job descriptions document the responsibilities and authority of all personnel. Figure 1 shows the organizational relationships at SSC.

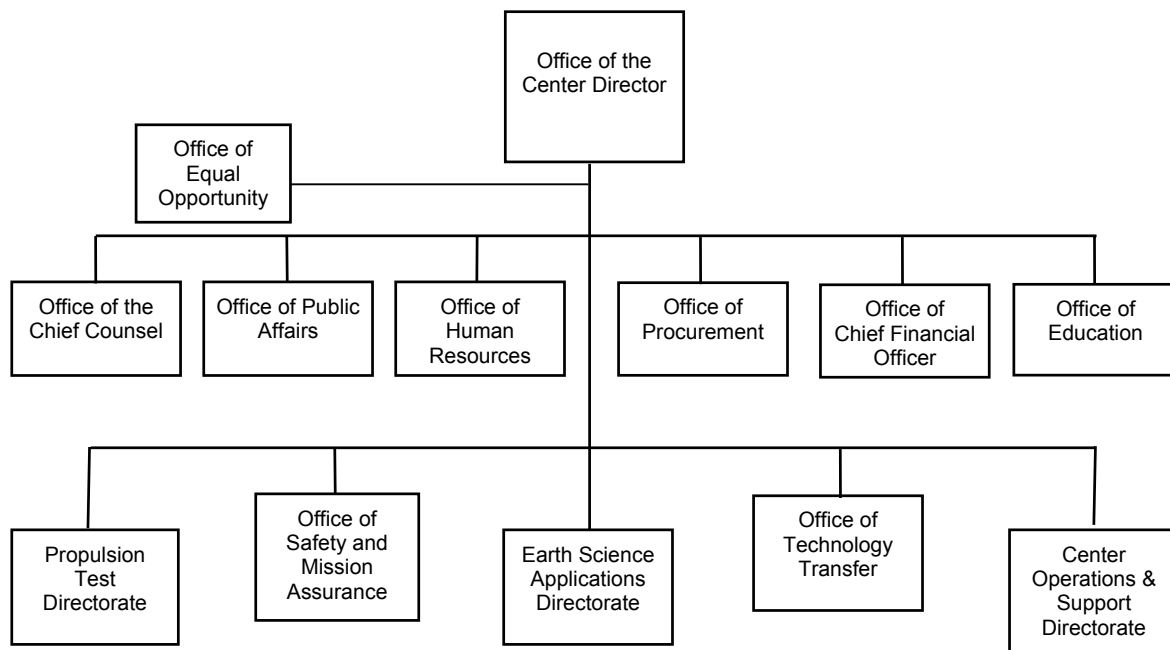


Figure 1-1. SSC Organization Chart

2.2 Quality Management System

2.2.1 General

The QMS is established, documented, maintained, and continually improved as a means of ensuring that SSC's products and services conform to the customer specified requirements and to ensure conformance to regulatory and obligatory requirements. SSC incorporated the

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requirements of ANSI/ISO/ASQ Q9001 and other NASA and SSC requirements in the preparation of this manual.

The controlled version is available on the World Wide Web (www) via the SSC Technical Documentation System (Tech Doc). By definition, any printed version of this SMM is uncontrolled. Proposed revisions to this manual are submitted to the Center Director.

The SMM includes or makes reference to the QMS procedures and outlines the structure of the documentation used in the QMS. Authority, applicability, and reference documents form a part of the citing document to the extent specified. Unless otherwise specified, the documents referred to are the latest approved versions. The SSC documentation hierarchy is defined in SPG 1400.1, Document Preparation, Numbering, and Management Guidelines and Standards.

2.2.2 Quality Management System Processes

The QMS is a formally documented system of planned activities established to provide evidence of compliance to the requirements of applicable regulations, codes, standards, specifications, drawings, and the SSC quality policy and quality objectives. All of these activities are managed in accordance with procedures and written instructions supported with records of objective evidence of satisfactory compliance. All organizations establish measures, as appropriate, to implement the SMM requirements. This includes the preparation of procedures and documentation that ensures compliance with the SMM and continual improvement of these processes. The following model illustrates the process approach:

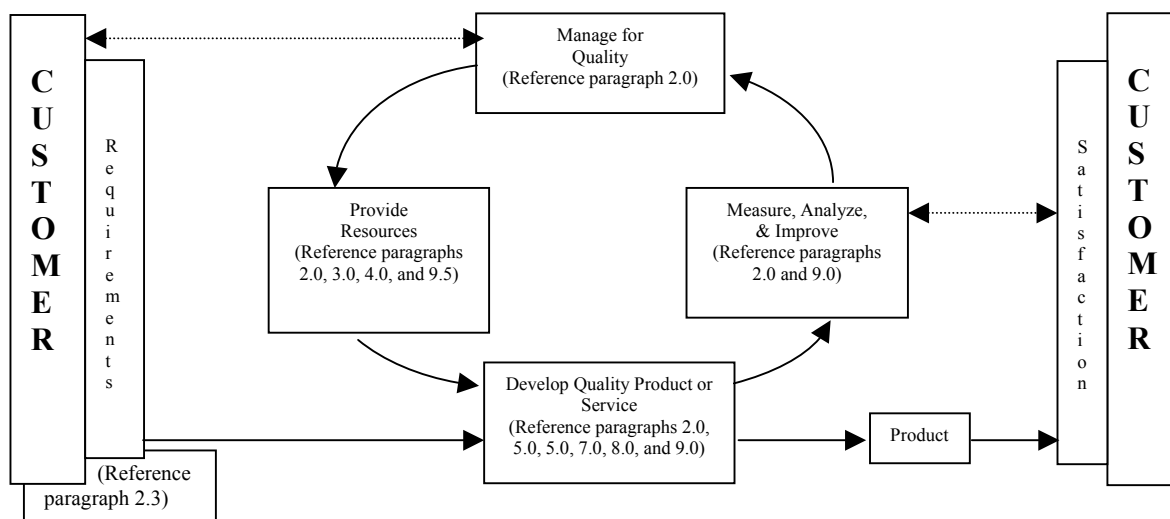


Figure 1-2. Process Model for SSC's Quality Management System

The range and detail of the procedures that form part of the QMS depend on the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying

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out the activity. Procedures may make reference to work instructions that define how an activity is performed.

SSC activities can be represented as a process or set of processes. Processes and their interactions are identified at appropriate levels of the organization in order to manage and document the quality system effectively.

2.2.3 Data Analysis

SSC determines, collects, and analyzes appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data provides information relating to:

- Customer satisfaction (see paragraph 2.3.5),
- Conformity to product requirements (see paragraph 9.3),
- Characteristics and trends of processes and products including opportunities for preventive action (see paragraph 2.5.5), and
- Suppliers (see paragraph 6.2 and 6.4).

2.2.4 Continual Improvement

SSC continually improves the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management reviews.

2.3 Customer-Related Processes

2.3.1 General

The directors and program/project managers ensure that customer requirements are understood and met with the aim of enhancing customer satisfaction. Procedures/instructions for customer-related processes, including contract (customer agreement) review and the coordination of these activities, are detailed in: SSLP-1050-0001, Customer Agreement, Review, and Coordination; SOI-8080-0006, Development and Approval of Customer Agreements; and SWI-1280-0002-ESAD, Customer Relations. These documents provide the methods of developing effective customer relations including measuring customer feedback and satisfaction.

2.3.2 Determination of Requirements Related To Products

SSC documents requirements specified by the customer, including the requirements for delivery and post-delivery activities; requirements not stated by the customer but necessary for specified

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or intended use, where known; statutory and regulatory requirements related to products; and any additional requirements determined by SSC.

2.3.3 Review of Requirements Related to Products

SSC reviews the requirements related to products. The reviews are conducted prior to SSC's commitment to supply a product to a customer (e.g., submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders). The reviews ensure that product requirements are defined, contract or order requirements differing from those previously expressed are resolved, and SSC has the ability to meet the defined requirements. Records of the results of these reviews and actions arising from these reviews are maintained.

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by SSC before acceptance. Where product requirements are changed, SSC ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

2.3.4 Customer Communication

Effective arrangements are made for communicating with customers in relation to product information. These include inquiries, contracts, or order handling, including amendments, customer feedback, as well as customer complaints.

2.3.5 Customer Satisfaction

As one of the measurements of the performance of the QMS, directors/project managers monitor information relating to customer perception as to whether SSC has met customer requirements. Active methods for obtaining and using this information are employed to obtain customer feedback. Active measures includes telephonic follow-up to mailed survey requests. Customer satisfaction is evaluated through the use of written surveys that provide numeric values.

2.4 Data Management, Including Document and Data Control

2.4.1 General

Documented procedures are established and maintained to identify/define, prepare, control, and disposition all documents and data that are within the scope of SSC's QMS including, to the extent applicable, documents of external origin such as standards and customer drawings. Procedural controls include requirements to periodically review, update as necessary, and re-approve documents. (Refer to SPG 1400.1, Document Preparation, Numbering, and Management Guidelines and Standard and SSLP-1410-0001, Document and Data Control.)

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All records are documented and retained, including disposition, in accordance with SSLP-1440-0001, SSC Records Management Program and Control of Quality Records and NPG 1441.1, NASA Records Retention Schedules. The SSC Tech Doc System is the official receipt, storage, and distribution point for SSC, standards, specifications, procedures, work instructions and handbooks.

The NASA Technical Standards Program's Agencywide Full-Text Technical Standards System serves as the master list for searching for information about various Technical Standards Products, including NASA Preferred Technical Standards. The Agencywide Full-Text Technical Standards System is accessible from the NASA Technical Standards Program's Web site at <http://standards.nasa.gov>.

Changes to technical standards can have major impacts on the safety and performance of SSC Programs and Projects. The Standard's Update Notification System (SUNS) is a Web-based system developed to notify NASA's Programs/Projects/Organizations and contractors within the "nasa.gov" domain of changes to standard products being used. The SUNS is also accessible from the NASA Technical Standards Program Web site at <http://standards.nasa.gov>.

2.4.2 Document and Data Approval and Issue

The adequacy and accuracy of documents and data are reviewed and approved prior to issuance to perform work by authorized management, or designee upon receipt of concurrence by the technical authorities and employee representatives performing the tasks. Each organization maintains the documents and data or identifies the repository location of the documents and data such that each employee who is performing the task can easily retrieve the applicable documents/data for use. These documents can be in the form of any type of media; electronic media is recommended when available. Master lists identifying the current revision status of documents, as well as previous versions authorized for use, are readily accessible from the Tech Doc System to preclude the use of invalid and/or obsolete documents. This control ensures that:

- a. Pertinent issues of appropriate documents are available at all locations essential to the effective functioning of the QMS.
- b. Invalid and/or obsolete documents are promptly removed from all points of issue or use, destroyed, or otherwise ensured against unintended use.
- c. Any previous/obsolete version of any documents within the SSC system retained by the user (e.g., for limited applicability, for historical purposes, for reference) are marked, or otherwise suitably identified.

2.4.3 Document and Data Changes

Changes, revisions, and cancellations to documents and data are reviewed and approved by the same SSC organizations that performed the original review and approval, unless designated otherwise. The designated SSC organizations performing review and approval have access to

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pertinent background information upon which to base their review and approval. Where practicable, a description of the change is identified in the document or in the appropriate attachments.

2.5 Process Control

2.5.1 Infrastructure

SSC management determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- Buildings, workspace, and associated utilities,
- Process equipment (both hardware and software), and
- Supporting services (such as transport or communications).

2.5.2 Control of Production and Service Provision

Procedures and instructions are developed on an ongoing basis by responsible organizations to ensure that functional activities are performed under controlled conditions. The methods for process controls for specific processes can be obtained through the Technical Documentation System. Process controls for hardware and software products are carried out in accordance with SLP-09, Process Control.

Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product,
- The availability of work instructions, as necessary,
- The use of suitable equipment,
- The availability and use of monitoring and measuring devices,
- The implementation of monitoring and measurement, and
- The implementation of release, delivery, and post-delivery activities.

2.5.3 Work Environment

SSC management determines and manages the work environment needed to achieve conformity to product requirements.

2.5.4 Validation of Processes for Production and Service Provision

Processes for production and service provision are validated where subsequent monitoring or measurement cannot verify the resulting output. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

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Validation demonstrates the ability of these processes to achieve planned results. Arrangements for these processes include, as applicable:

- Defined criteria for review and approval of the processes,
- Approval of equipment and qualification of personnel,
- Use of specific methods and procedures,
- Requirements for records, and
- Revalidation.

2.5.5 Monitoring and Measurement of Processes

Suitable methods for monitoring and, where applicable, measurement of the QMS processes are defined by management. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken, as appropriate, to ensure conformity of product. (See paragraphs 2.6, 9.2, and 9.5.)

2.6 Corrective and Preventive Action

2.6.1 General

Documented procedures are established and maintained to ensure consistent and effective methods for correction and prevention of recurrence of nonconformances. A consistent procedure to ensure that nonconformances are corrected is necessary for the delivery of a quality product to the customer. Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities is appropriate to the magnitude of problems and commensurate with the risks encountered. Any changes to the documented procedures as a result of corrective or preventive actions are recorded and implemented.

2.6.2 Corrective Action

Effective handling of customer concerns or complaints and reports of product nonconformances is done according to documented procedures. (Refer to SSLP-8730-0004, Corrective/Preventive Action and Improvement.) Disciplined problem-solving methods are used during investigation of cause for nonconformance to specifications or requirements relating to product, process, and management system. Results of the investigation and analysis are recorded. Procedures are established for determination of corrective action needed to eliminate the cause of nonconformances and define corrective action follow-up activity to ensure documented corrective action is taken and that it is effective.

2.6.3 Preventive Action

Preventive action eliminates the causes of potential nonconformities to preclude their occurrence. It is applied as appropriate to mitigate potential problems. Documented procedures define

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requirements for: determining potential nonconformities and their causes; evaluating the need for action to prevent occurrence of nonconformities; determining and implementing action needed; records of results of actions taken; and reviewing preventive action taken. (Reference SSLP-8730-0004, Corrective/Preventive Action and Improvement.)

2.7 Internal Audits

The MRQ establishes and maintains documented procedures for planning and implementing internal quality audits. (Refer to SSLP-1280-0004, Internal Quality Audits.) Internal audits are used to ensure conformity of the QMS, and to continually improve the effectiveness of the QMS through corrective actions taken by the audited organizations.

SSC plans and performs internal audits on a scheduled basis, taking into consideration the status and importance of the processes and areas to be audited, as well as results of previous audits. The results are documented and maintained as records and distributed to affected organizations. Identified nonconformances are tracked to ensure that the management of the affected area takes timely corrective action.

Personnel not assigned to the activity under review perform audits. Audits are performed to determine compliance with ISO 9001, documented procedures, plans, instructions, and accepted customer agreements. The internal audits also are used to determine the effectiveness of the QMS.

Follow-up audits are performed by SSC to verify and record the implementation and effectiveness of the corrective action taken and are maintained as quality records. Corrective action commitments made in response to audit findings are assessed to ensure implementation and effectiveness of the action.

The results of audits are an integral part of the input to the management review activities (see SSLP-1280-0001, Internal Quality Audits).

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CHAPTER 3. LEGAL AND TECHNICAL PROCESSES

3.0 Legal and Technical (2000-2999)

The following activities are managed in accordance with the Legal and Technical series:

- General (20XX)
- Technology Utilization (21XX)
- Scientific and Technical Information (22XX)
- Management Information Systems (23XX)
- ADP Management (24XX)
- Communications (25XX)
- Photographic Services Management (26XX)
- Information Technology Management (28XX)

3.1 Legal

The SSC Office of the Chief Counsel has established and maintains appropriate procedures, office issuances, and records for the implementation, generation, and control of legal and patent functions/processes.

The Office of the Chief Counsel activities are managed in accordance with the Legal and Technical series: General (20XX).

3.2 Technical

Management and operation of SSC's scientific and technical information programs, including the Office of Technology Transfer are defined in documented procedures and records.

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CHAPTER 4. HUMAN RESOURCES AND PERSONNEL MANAGEMENT PROCESSES

4.0 Human Resources/Personnel (3000-3999)

SSC maintains documented procedures/instructions for the management and operations of NASA personnel functions.

Personnel management activities are performed in accordance with the following Human Resources/Personnel series:

- General (30XX)
- Executive Human Resources Management (31XX)
- General Personnel Provisions (32XX)
- Employment (General) (33XX)
- Employee Performance and Utilization (34XX)
- Position Classification, Pay, and Allowances (35XX)
- Time and Attendance (36XX)
- Personnel Relations and Services (37XX)
- Insurance and Annuities (38XX)
- General and Miscellaneous (39XX)

SSC maintains documented procedures that identify the competency level and training needs of each job and/or function. Appropriate training of personnel is also provided. (Refer to SSLP-3410-0001, Training and SCWI-3410-0002, Training and Development Plan.) Appropriate records of education, training, skills, and experience are maintained as quality records.

Personnel performing work affecting product quality will be competent on the basis of appropriate education, training, skills, and experience. SSC determines the necessary competence for personnel. SSC provides training or takes other actions to satisfy these needs and evaluate the effectiveness of the actions taken. Personnel are informed of the relevance and importance of their activities and how they contribute to the achievement of the objectives, including quality objectives.

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CHAPTER 5. PROPERTY AND SUPPLY MANAGEMENT PROCESSES

5.0 Property and Supply (4000-4999)

5.1 Government Property

SSC maintains documented procedures/instructions for the management and operation of NASA property and supply management functions.

The following activities are managed in accordance with the Property and Supply series:

- General (40XX)
- Inventory Management (41XX)
- Equipment Management (42XX)
- Utilization and Disposal (43XX)
- Supply Cataloging (44XX)
- Storage and Distribution (45XX)
- Expanded Supply Control (46XX)

5.2 Control of Customer-Supplied Product

SSC exercises care with property belonging to an external customer while it is under SSC's control. To ensure control of customer-supplied products, SSC establishes and maintains documented procedures for the control, verification, storage, and maintenance and return of any customer-supplied products. (Refer to SSLP-4210-0001, Control of Customer Property.) Unless specified otherwise by the customer, all customer-supplied products, from time of receipt until the time they are transferred out of the SSC QMS, are handled in accordance with the requirements and procedures applicable to SSC hardware of the same classification.

External customer-supplied products that are lost, damaged, or are found to be otherwise unsuitable for use, are formally reported to the customer.

Customer property can include intellectual property. Proprietary/confidential documentation received by SSC is controlled in accordance with SOI-8074-0001, Protection of Critical Information Resources.

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CHAPTER 6. PROCUREMENT/SMALL BUSINESS/INDUSTRIAL RELATIONS PROCESSES

6.0 Procurement/Small Business/Industrial Relations (5000-5999)

SSC establishes and maintains documented procedures/instructions for the management and operation of NASA procurement and contracting functions.

The following activities are managed in accordance with the Procurement/Small Business/Industrial Relations series:

- Procurement/Small Business/Industrial Relations (50XX)
- Procurement (Contracts) General (51XX)
- Contractor Labor Relations (52XX)
- Reliability and Quality Assurance (53XX)
- Contractor-Held Government Property (54XX)
- Patent Waiver (55XX)
- Statement of Work (56XX)
- Awards, Inventions, and Contributions (57XX)
- Grants and Cooperative Agreements (58XX)
- Contractor Financial Management and Reporting (59XX)

6.1 Purchasing

SSC maintains documented procedures to ensure that purchased products and services conform to specified requirements. (Refer to SPD 5100.1, Policy for Ordering Materials and Support Services at Stennis Space Center.) Procedures shall ensure that materials received conform to the applicable drawings, specification, and quality standards. Verification methods employed are: Quality System Surveys and Audits, Source Inspections, Supplier Performance Evaluations, and inspections and test of materials upon receipt. Outsourced processes that can affect product conformity are also controlled by procedures.

SSC personnel adhere to the following regulations and guidelines for all SSC procurements:

- a. NASA procurements are conducted in accordance with the Federal Acquisition Regulation (FAR) and the NASA FAR Supplement.
- b. Contractor procurements are conducted in accordance with the contractor's company purchasing procedures and standard commercial practices and contain appropriate FAR flow-down clauses.
- c. Where appropriate and beneficial to NASA, contractors are contractually required to have quality systems that comply with or are registered to the ISO 9001 standard.

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6.2 Assessment of Contractors

SSC evaluates and selects contractors on the basis of their ability to meet all specified requirements including performance, cost, and schedule, as well as the quality system and any specific quality assurance requirements. Criteria for selection, evaluation, and re-evaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained in the contract file. The various methods used in this assessment are:

- Quality System Evaluations and/or Surveys,
- Past Performance Evaluations and Customer Questionnaires, and
- Capability or Mission Suitability Evaluations.

The type and extent of control exercised over contractors are defined in the appropriate contract file. The type and extent of control will be dependent upon the type of product, the effect of the purchased product or services on subsequent product realization, and the impact on the quality of the final product.

6.3 Purchasing Data

Purchasing documents clearly describe the product ordered including, where applicable:

- a. The type, class, grade, or other precise identification;
- b. The title of other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions, and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment, and personnel; and
- c. The title, number, and issue of the Quality System standard to be applied.

SSC reviews and approves purchasing documents for adequacy of the specified purchase requirements prior to their communication to the supplier. (Refer to SLP-06, Purchasing.)

6.4 Verification of Purchased Product

SSC has established and implemented inspection or other activities necessary for ensuring that the purchased product meets specified purchase requirements. (Reference SSLP-1280-0010, Inspection and Testing.)

Where SSC or its customer proposes to verify the purchased product at the supplier's premises, SSC shall specify verification arrangements and the method of product release in the purchasing documents.

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CHAPTER 7. TRANSPORTATION MANAGEMENT PROCESSES

7.0 Transportation (6000-6999)

Management and operation of NASA transportation functions is documented in appropriate procedures and/or instructions.

Transportation activities are managed in accordance with the following series:

- General (60XX)
- Commercial Freight Services (61XX)
- Traffic Management Programs (62XX)
- Transportation of Unusual or Hazardous Cargo (63XX)
- Preparation and Handling of Cargo (64XX)
- Special Airlift Services (65XX)
- Transportation and Transport Engineering (66XX)
- Motor Vehicle Operation and Management (67XX)
- Passenger Transportation (68XX)

SSC maintains documented procedures for handling, storage, packaging, preservation, and delivery of products that are within the scope of SSC's QMS. (Refer to SLP-15, Handling, Storage, Packaging, Preservation, and Delivery.)

Handling methods to prevent damage and deterioration, including Electrostatic Static Discharge (ESD) handling and precautions, are implemented and updated routinely.

Controlled storage and stock areas are utilized to prevent damage, loss, or deterioration of materials and products. Procedures are documented for authorizing the receipt and dispatch to and from these areas. Access to storage areas is limited to authorized personnel. Special provisions are established and implemented for EDS, age-sensitive materials, and items stored requiring environmental controls. Periodic assessment of in stock product condition to detect deterioration is conducted.

Documented procedures and/or packaging plans are initiated to define the controls and verification applied to the preservation, packaging, and marking processes (including materials used) to ensure compliance with specified requirements. Appropriate methods for preservation and segregation of products are applied when the product is under SSC control. The quality of product is ensured after inspection and test and protection extends to include delivery to destination.

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CHAPTER 8. PROGRAM FORMULATION PROCESSES

8.0 Program Formulation (7000-7999)

SSC maintains appropriate documented procedures/instructions for the management, planning, and administration of research and development programs and groups of projects and laboratory type organizations.

The following activities are managed in accordance with the Program Formulation series:

- General (70XX)
- Research and Development Planning and Approval (71XX)
- Institutional Planning and Approval (72XX)
- Facility Planning and Approval (73XX)
- Budget Formulation and Execution (74XX)
- Commercialization (75XX)
- Program Operating Plans (76XX)
- Human Resources Utilization (77XX)
- Resources Authority Allocation System (78XX)
- Aircraft Operations and Management (79XX)

8.1 Program/Project and Quality Planning

SSC defines and documents how requirements will be met for each project, program, or activity within our defined scope. Program/Project and quality planning is consistent with all other requirements of SSC's QMS and is documented in a format to suit SSC method of operation. Program/Project and quality planning is performed per SPD 7120.1, SSC Program/Project Planning Risk Management and SPG 7120.1, SSC Risk Management.

In planning product realization, SSC determines the following, as appropriate:

- a. Objectives, including quality objectives, and requirements for product;
- b. The need to establish processes, documents, and provide resources specific to the product;
- c. Required verification, validation, monitoring, inspection, and test activities specific to the product and the criteria for product acceptance;
- d. Records needed to provide evidence that the realization processes and resulting product meet requirements.

8.2 Configuration and Data Management

Configuration and data management are applied, with the optimum degree of uniformity, to all programs and projects procured through contracts or acquired through in-house activities. The

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configuration and data management activities that fulfill the requirements of NPG 7120.5, Program and Project Management Processes and Requirements are documented and implemented in accordance with SOI-8080-0015, Configuration Control of Propulsion Test Systems.

8.3 Risk Management

All programs/projects are required to prepare a risk management plan during the program/project formulation phase. This plan may be a supplement of the program/project plan. Each program/project will follow a continuous risk management process. This process is iterated throughout the program/project life cycle. (Reference SPD 7120.1, SSC Program/Project Risk Management.)

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CHAPTER 9. PROGRAM MANAGEMENT PROCESSES

9.0 Program Management (8000-8999)

NASA requires that Centers have a well-defined system for integrated planning, approval, and implementation of programs to ensure they are consistent with Agency and Center strategic planning, available resources, and conducted in accordance with established commitments. SSC appropriately applies the principals of NPG 7120.5, Program and Project Management System Requirements in the management of its programs/projects.

SSC maintains documented procedures/instructions for the management, operation, and performance of basic and applied research and engineering development projects. SSC also maintains documented procedures and instructions for the management and operation of NASA construction of facilities, and architectural, and engineering design functions.

The following activities are managed in accordance with the Program Management series:

- General (80XX)
- Advanced Studies (81XX)
- Supporting Research and Technology (82XX)
- Grants and Research Contracts (83XX)
- Tracking and Data Acquisition (84XX)
- Environmental Management (85XX)
- Operations (86XX)
- Safety and Mission Assurance (87XX)
- Real Property and Facilities (88XX)
- Program Medical Support (89XX)

9.1 Design and Development

9.1.1 General

SSC design and development procedures control and verify the design of all products (hardware and software) and facilities, as well as control research, technology and development activities (RT&D), within the scope of SSC's QMS to ensure that specified requirements are met.

Procedures pertaining to design of propulsion hardware and associated ground/test support equipment are defined in SSLP-8060-0001, Design Control, and SOI-8080-0015, Configuration Control of Propulsion Test Systems. Design of facilities is addressed in PTD-OI-E05, Facility Design Requirements. Procedures for research, technology, and development activities are defined in RA-97-02, Facilities Construction Configuration Management Manual.

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9.1.2 Design and Development Planning

Design and development activities are assigned to qualified personnel equipped with adequate resources. SSC prepares plans commensurate with contracts or Space Act Agreements for each design and development activity. The plans describe or reference these activities and define responsibility for their implementation. The design and development stages and the appropriate reviews, verification, and validation are determined during planning. The plans for projects are in accordance with SSLP-8060-0001, Design Control, and the guidelines established by OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Standards, for selection of design specifications and standards.

In the formulation phase, SSC Programs/Projects shall evaluate use of non-Government voluntary consensus standards in lieu of Government-unique standards in their procurements and regulatory activities, except where inconsistent with law or otherwise impractical, per OMB Circular A-119 and SSTD-8070-0005-CONFIG, Preparation, Approval and Release of Standards. Use of non-Government voluntary consensus standards is not required where they would fail to serve NASA's program/project needs.

Nonflight hardware and facility design planning will be in accordance with SSLP-8060-0001, Design Control and PTD-OI-EO5, Facility Design Requirements, respectively. The plans will be updated as the design evolves.

9.1.3 Organizational and Technical Interfaces

Organizational and technical interfaces between groups, which input into the design process, are defined and the necessary information documented, transmitted, and regularly reviewed.

9.1.4 Design and Development Inputs

Design and development inputs are identified, documented, and reviewed by each appropriate department or office for adequacy and accuracy. These inputs include functional and performance requirements, applicable statutory and regulatory requirements, information derived from previous similar designs (where applicable), and other requirements essential for design and development. Ambiguous, incomplete, or conflicting requirements are resolved with those responsible for imposing the requirements. The results of the contract review are considered during design input. Any changes agreed to will be documented and approved.

9.1.5 Design and Development Outputs

Design and development outputs are documented and expressed in terms that can be verified against the design and development input requirements and validated. The design outputs shall meet the design and development input requirements, contain or reference acceptance criteria, and identify critical design characteristics crucial for the safe and proper functioning of the

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product. This includes appropriate information for purchasing, production, and for service provision, as well as, operating, storage, handling, maintenance, and disposal requirements. All design output documentation is reviewed and approved prior to release.

9.1.5 Design and Development Review

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements to evaluate the ability of the results of design and development to meet requirements, and to identify any problems and propose necessary actions. Participants in such reviews shall include representatives of functions involved with the design and development stages being reviewed. Records of the results of the reviews and any necessary actions are maintained.

9.1.6 Design and Development Verification

Verification is performed in accordance with planned arrangements (see paragraph 9.1.2) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

9.1.7 Design and Development Validation

Design and development validation is performed in accordance with planned arrangements (see paragraph 9.1.2) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions are maintained.

9.1.8 Control of Design and Development Changes

Design and development changes are identified and records maintained. The changes are reviewed, verified, and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and products already delivered. Records of the results of the review of changes and any necessary actions are maintained.

Changes and modifications to designs and specifications are in accordance with SSLP 8060-0001, Design Control and PTD-OI-EO5, Facility Design Requirements, respectively.

9.2 Product Identification and Traceability

Where appropriate, SSC maintains documented procedures for identifying the product throughout product realization. (Refer to SLP-08, Product Identification and Traceability.) SSC

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maintains documented procedures for unique identification of individual products or batches requiring traceability. Records of such identification are maintained.

9.3 Monitoring and Measurement of Product

Documented procedures are maintained for inspection and testing activities to verify that the specified requirements for products are met. (Refer to SSLP-1280-0010, Inspection and Testing.) The required inspection and testing, and the records to be established, are detailed in the quality plan or documented procedures.

Product characteristics are monitored and measured to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product.

Product release and service delivery shall not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable, by the customer.

9.4 Control of Monitoring and Measuring Devices

Monitoring and measurement activities to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements are documented in SSLP-8720-001, Control of Inspection, Measurement, and Test Equipment. Documented procedures ensure that monitoring and measurement can be accomplished and are accomplished in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:

- a. Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verifications are recorded;
- b. Adjusted as necessary;
- c. Identified to enable the calibration status to be determined;
- d. Safeguarded from adjustments that would invalidate the measurement result and;
- e. Protected from damage and deterioration during handling, maintenance and storage.

In addition, SSC assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. SSC takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained.

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When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

9.5 Inspection and Test Status

The inspection and test status of the products is identified by suitable means, which indicate the conformance or nonconformance of products with regard to inspections and tests performed. The identification of inspection and test status is maintained, as defined in the quality plan and/or documented procedures, throughout production, installation, and servicing of the product to ensure that only products that have passed the required inspections and tests or released under an authorized concession are dispatched, used, or installed. Activities relating to inspection and test status are performed in accordance with SSLP-1280-0010, Inspection and Testing.

9.6 Control of Nonconforming Product

9.6.1 General

Documented procedures are maintained to ensure that a product that does not conform to specified requirements is prevented from unintended use, delivery, or installation. (Refer to SLP-13, Control of Nonconforming Product.) Controls provide for identification, documentation, evaluation, segregation, and disposition of nonconforming product and for notification to the directorate concerned.

9.6.2 Review and Disposition of Nonconforming Product

Responsibility for review and authority for the disposition of nonconforming product is defined in SLP-13, Control of Nonconforming Products. Nonconforming product is reviewed in accordance with documented procedures for rework to meet requirements, accept with or without repair, regarded for alternative applications, or reject/scrap. The proposed use or repair of product that does not conform to specified requirements is reported to the customer or customer's representative for approval. A description of the nonconformity that has been accepted and all repairs are recorded. Any repaired or reworked product is inspected by the appropriate personnel in accordance with the quality plan and/or documented procedures. Actions appropriate to the effects, or potential effects, of the nonconformity are taken when started. Quality records for the identification, documentation, evaluation, segregation, and disposition of nonconforming product/services will be maintained.

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CHAPTER 10. FINANCIAL MANAGEMENT PROCESSES

10.0 Financial Management (9000-9799)

The Office of the Chief Financial Officer provides an automated financial management operation and a comprehensive planning, programming, budgeting, and resource authority control system for SSC, assuring the SSC Director that the missions and objectives are accomplished in accordance with established policies and procedures. The applicable policies, procedures, and regulations can be found at URL: <http://sscweb.ssc.nasa.gov/cfo/functions.htm>.

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CHAPTER 11. RECORDS

Records requirements are defined in the appropriate reference documents.

Records management activities are performed in accordance with NPD 1440.6, NASA Records Management; NPG 1441.1, NASA Records Retention Schedules; and SSLP 1440-0001, SSC Records Management Program and Control of Quality Records. To ensure control of records:

- a. SSC has established and maintains documented procedures for the identification, collection, indexing, filing, storage, accessing, maintenance, and disposition of quality records.
- b. Records, including pertinent records from SSC customers and suppliers, are maintained to demonstrate conformance to specified requirements and the effective operation of the QMS.
- c. SSC ensures quality records are legible, stored and retained in such a way that they are readily retrievable and not subject to damage, deterioration, or loss. Retention times are established and recorded in accordance with NPG 1441.1, NASA Records Retention Schedules.

Where agreed with the customer, quality records are made available to the customer for evaluation for an agreed period. The SSC Master Records Index database contains a complete list of records.

The below table cross references SSC records specifically identified in the ISO 9001 Standard to the appropriate standard paragraph. These records are often referred to as quality records.

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Table 11-1. Cross-reference Between ISO 9001 and SSC Quality Records

ISO 9001-2000 Paragraph	SSC Document Number Series	Record Title
5.6.1 – Management Review	• 1280.02	• Quality Management Council Minutes
6.2.2 – Human Resources	• 3410 • 3410.4 • 9603	• Training Records on Training & Cert Record System • Training Certification Records System (TCRS)(NASA) • Training Certification Records Systems (TCRS)
7.2.2 – Review of Requirements	• 7000 • 8080	• Project Plans • Program Requirements Document
7.3.2 – Design and Development Inputs	• 8080.18 • 8810	• Design Reviews – Official File • Design Engineering Folders
7.3.5 – Design and Development Verification	• 8080.11	• Verification & Validation Reports
7.4.1 – Purchasing process	• 5100 • 5109	• Contracts and Purchase Orders for \$100,000 or Less • Contracts and Purchase Orders for over \$100,000 • Contract Files
7.5.2 – Validation of process for production and service provision	• 8080 • 8080.4 • 8080.7 • 8080.8 • 8080.9	• Correspondence – Official File • Test Plan – Official File • Test Readiness Reviews • Detailed Operating Procedures • Test Preparation Sheets
7.6 – Control of monitoring and measuring devices	• 5100	• Stennis Work Request
8.2.2 – Internal Quality Audits	• 1280.01	• Internal Quality Audits
8.2.4 – Monitoring and measurement of product	• 8080.10 • 8080.10 • 8830/5213.6	• Test Reports • Test Packages • Test Readiness Checklist
8.3 – Control of non-conforming product	• 5001 (4000) • 5300	• Discrepancy & Corrective Report • Discrepancy & Corrective Report
8.5.2 – Corrective Action	• 5001.1 • 8080.6	• Corrective Action Request (CAR) • Discrepancy Reports (DR's)
8.5.3 – Preventive Action	• 1280.06	• Corrective Action Requests

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CHAPTER 12. MEASUREMENT

Measurements for the SSC QMS as defined in paragraph P.1: Demonstrate conformity of all products and services; conformity of the QMS; and the effectiveness of the QMS' continual improvement. Methods of monitoring, measurement, analysis, and improvement include:

- a. Internationally recognized third-party certification to the ISO 9001 standard in accordance with NPD 8730.3, NASA Quality Management System Policy (ISO 9000).
- b. Ongoing maintenance as measured by subsequent successful re-certifications.
- c. Customer satisfaction as reflected in paragraph 2.3.
- d. SSC internal quality audits of the QMS in accordance with paragraph 2.7.
- e. Processes used to provide SSC products and services as explained in paragraph 2.5.
- f. Products and services provided by SSC and introduced in paragraph 9.2.

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Appendix A Acronyms

AFS	Agency Filing Scheme
ANSI	American National Standards Institute
ASQC	American Society for Quality Control
CAR	Corrective Action Report
DR's	Discrepancy Reports
ESAD	Earth Science Applications Directorate
ESD	Electrostatic Discharge
FAR	Federal Acquisition Regulation
ISO	Greek meaning equal
MRQ	Management Representative for Quality
NPG	NASA Procedures and Guidelines
NPD	NASA Policy Directive
NODIS	NASA Online Directives and Information System
OMB	Office of Management & Budget
PT	Propulsion Test
PTD	Propulsion Test Directorate
QMS	Quality Management System
RT&D	Research, Technology & Development
S&MA	Safety & Mission Assurance
SCWI	Stennis Common Work Instruction
SDL	Stennis Distribution List
SLP	System Level Procedure
SMM	Stennis Management Manual
SOI	Stennis Organization Instruction
SPD	Stennis Policy Directive
SPG	Stennis Procedures and Guidelines
SSC	Stennis Space Center
SSLP	Stennis System Level Procedure
SUNS	Standard's Update Notification System
TCRS	Training and Certification Records System
TDS	Technical Documentation System
WI	Work Instruction
www	World Wide Web

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Appendix B Definitions

In general, the definitions given in ANSI/ISO/ASQ Q9000-2000 apply. However, the following definitions are offered to assist the user in understanding the application of the ISO 9001 quality standard at SSC.

Customer: The recipient of a product or service provided by SSC. For the purpose of the QMS the customer is external to SSC. The words "Customer" and "Partner" are used interchangeably.

Customer Agreement (CA): The documented agreement between SSC and the Customer or Partner establishing the requirements of a desired service or collaboration, and the manner in which the desired service or collaboration is provided. Customer Agreements may take many forms, such as a Reimbursable or Non-reimbursable Space Act Agreement, a Task Agreement, a Memorandum of Understanding, etc.

Design Review: A documented, comprehensive, and systematic examination of a design to evaluate its capability to fulfill the requirements for quality; to identify problems, if any; and to propose the development of solutions. A design review can be conducted at any stage of the design process, but should, in any case, be conducted at the completion of the design stage.

ISO: Borrowed from the Greek word, *isos*, meaning, "equal." It refers to the International Organization for Standardization, which was founded in 1946 to develop a common set of manufacturing, trade, and communication standards. Although this organization is commonly referred to as ISO, *ISO* technically is not an acronym for anything.

Management Representative for Quality (MRQ): A person who is responsible for ensuring the effective establishment and operation of the SMM, and who reports directly to the QMC.

Master List: Listing of work instructions, forms, etc. used to perform tasks. It contains the document's number and revision level.

Product: Results of activities or processes. A product may include service, hardware, processed materials, software, or a combination thereof. A product can be tangible (e.g., assemblies or processed materials), intangible (e.g., knowledge or concepts), or a combination thereof. For the purposes of the ISO standards, the term "product" applies to the intended product offering only, and not to unintended by-products affecting the environment.

Project Manager: The Project Lead and Primary Point of Contact (POC) who provides the interface between the Customer or Partner and Stennis Space Center, i.e. all Stennis Space Center organizations. The Project Manager may delegate Point of Contact duties to alternate persons.

Quality: The degree to which a set of inherent characteristics fulfills requirements.

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Quality Management: The coordinated activities to direct and control an organization with regards to quality. All activities of the overall management function that determine the quality policy, objectives, and responsibilities, and that implement them by means such as quality planning, quality control, quality assurance, and quality improvement.

Quality Management Council (QMC): The Council manages the implementation, maintenance, and effectiveness of the quality system. This management team renders decisions, assigns actions, and tracks those actions to closure. The Council's membership is defined in SPG 1152.1, SSC/NASA Charter – Boards/Councils/Committees.

Quality Management System: The interrelated methods through which top management directs and controls the organization with regards to quality.

Quality Objective: Something sought, or aimed for, related to quality.

Quality Plan: A document setting forth the specific quality practices, resources, and sequence of activities relevant to a particular product, project, or contract.

Quality Policy: The overall intentions and direction of an organization with regard to quality as formally expressed by top management.

Quality Record: A document or data item that furnishes objective evidence of activities performed or results achieved. A quality record substantiates the fulfillment of quality requirements or the effectiveness of a QMS element's operation. Some of the purposes of quality records are demonstration, traceability, and preventive and corrective action. A quality record can be written or stored on any data medium.

Quality System: The organizational structure, procedures, processes, and resources needed to implement quality management.

Top Management: The person or group of people who directs and controls an organization at the highest level of that organization.

Validation: Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

Verification: Confirmation by examination and provision of objective evidence that specified requirements has been fulfilled.